

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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Certifier N. Hawkins

**New Animal Drugs For Use In Animal Feeds; Nicarbazin, Narasin, and Bacitracin
Methylene Disalicylate**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for using approved two-way narasin/nicarbazin and single-ingredient bacitracin methylene disalicylate (BMD) Type A medicated articles to make three-way, combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, has filed NADA 141-124 that provides for the combination use of approved MAXIBAN (36 grams per pound (g/lb) each of narasin and nicarbazin) and BMD (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate) Type A medicated articles in three-way, combination drug Type C medicated feeds for broiler chickens. The Type C feeds containing 27 to 45 g/ton each narasin and nicarbazin and 50 g/ton bacitracin methylene disalicylate are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the prevention of necrotic enteritis caused or complicated

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NFR-1

by *Clostridium* spp. or other organisms susceptible to bacitracin. The Type C broiler feeds containing 27 to 45 g/ton each narasin and nicarbazin and 100 to 200 g/ton BMD are used for the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. The NADA is approved as of January 14, 2002, and the regulations in 21 CFR 558.76 and 558.366 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.76 [Amended]

2. Section 558.76 *Bacitracin methylene disalicylate* is amended in paragraph (d)(3)(xii) by adding “or narasin” after “narasin”.

3. Section 558.366 is amended in the table in paragraph (d), in the column for “Combination in grams per ton” after the entry for “Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50” by adding entries for “Narasin 27 to 45 and bacitracin methylene disalicylate 50” and “Narasin 27 to 45 and bacitracin methylene disalicylate 100 to 200” to read as follows:

§ 558.366 Nicarbazin.

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(d) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
	Narasin 27 to 45 and bacitracin methylene disalicylate 50.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylene disalicylate by No. 046573 in § 510.600(c) of this chapter.	046573

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
	Narasin 27 to 45 and bacitracin methylene disalicylate 50.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylene disalicylate by No. 046573 in § 510.600(c) of this chapter.	046573
	Narasin 27 to 45 and bacitracin methylene disalicylate 100 to 200.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylene disalicylate by No. 046573 in § 510.600(c) of this chapter.	046573
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Dated: 4/9/02
April 9, 2002

SF Sundlof
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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